Exhibit 1

Expert Report of Karla Ballman, Ph.D.
for Eli Lilly and Company
In re: Viagra (Sildenafil Citrate) Product Liability Litigation

P1.0211.1

Random error is due to chance alone, which is measured by a p-value. The p-value indicates the chance that an observed result arose from chance alone rather than due to another influence such as the risk factor of interest. For example, if there is no systematic error, the p-value measures the likelihood of observing an association, say between UV exposure and risk of melanoma, if in reality there is no association. If this value is small (typically set at less than 0.05), and there is no systematic error, the conclusion is that there must be an association, because there is little chance it arises from chance alone.[1] In the hypothetical example, if the p-value for the association between UV exposure and risk of melanoma is 0.01, this means that if there were no association, the chance is 1 in 100 for obtaining the association that was observed. Most statisticians would say the observed association is unlikely to be found as a result of chance alone: there is only a 1 in 100 chances that the finding – in this example, an association between UV and melanoma – is the result of chance, implying that the assumption of "no association" must be untrue. If there is systematic error, the p-value is difficult to interpret. If it is significant (meaning less than 0.05), it could be because of a real association, or because of the systematic error, or a combination of both. All studies need to be carefully evaluated for confounding and the degree they are representative of the general population before interpreting the p-value.

B.   Levels of evidence

Cancer epidemiology attempts to identify risk factors that are causative agents of cancer. Knowing what causes a cancer may lead to therapies that benefit patients and/or strategies to minimize the exposure to a risk factor. There are different levels of evidence for determining whether a factor is causal based on the underlying study design. A recognized ranking of common study designs from greatest level of evidence to lowest is (1) randomized clinical trials, (2) cohort and case-control studies, and (3) case reports and case series.

1.   Randomized clinical trials

Randomized clinical trials offer the highest level of evidence for a causal factor. In randomized trials, patients are assigned to a treatment arm or a control arm via a random number generator that mimics a coin flip. Randomization makes the two groups as similar as possible across all factors except for the treatment/intervention imposed by the investigator. Since the only difference between the groups is the administered intervention, any observed difference in outcomes between the groups can be attributed to the intervention. A randomized clinical trial provides evidence that the intervention is

---

[1] Dr. Liu-Smith is not correct in suggesting that it is "standard methodology in epidemiology" to consider odds ratios (p. 6) "regardless of statistical significance." It is standard methodology in epidemiology to calculate and report whether a result is statistically significant ($p = <.05$) as a test of the likelihood that the result(s) may be due to chance.

P1.0211.2

issue, or medical or scientific institutions or regulators, that causation or exacerbation of melanoma by PDE5i use in humans has been shown, except by Plaintiffs' experts for purposes of this litigation.

Karla V. Ballman

_____

Karla Ballman, Ph.D.

June 8, 2018

47

P1.0211.3